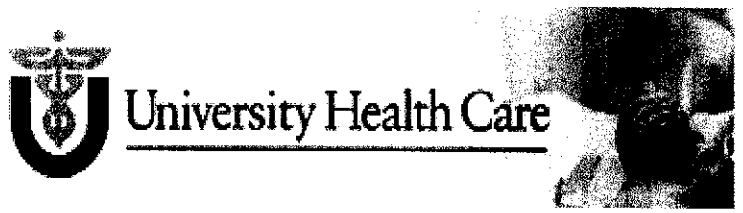
K080551



MAY 28 2008

Pre-Market Notification 510 (K) Summary

Submitter Name: University of Utah Hospitals and Clinics
50 North Medical Drive
Salt Lake City, UT 84132

Contact: Brent Alm
University of Utah Hospitals and Clinics
50 North Medical Drive
Salt Lake City, UT 84132
801-581-2847

FDA Registration: 3004595606

Device Name: Trade Proprietary Name - University Health Care Reprocessed Alternating Leg Pressure (UHC APL) sleeve device

Common or Usual Name – (ALP®) Alternating Leg Pressure Device

Classification: Class II: Medical Device
Regulation: 21 CFR 870.5800
Panel Number: Panel 70
Product Code: JOW
Classification Name: Sleeve, Limb, Compression

Predicate Device: Healthcare Service and Supply ALP® Alternating Leg Pressure Garment K000303

ReNu Medical Reprocessed ALP® Calf Garment K051227

UUHC's Reprocessed Compression Sleeve Device K031189

Device Description: UHC APL is the compression sleeve component of a non-invasive external compression system consisting of a pump/controller, connecting tube and limb sleeve/garment device.

Intended Use: To be used for patients for whom external compression therapy is indicated for the prevention of deep vein thrombosis and resulting pulmonary embolism due to the present risk factors for thrombosis formation.

Technical Characteristics: The UHC APL reprocessed sleeve device is substantially equivalent in overall design, materials, energy source, mode of operation, performance technique, and reprocessing methods as the predicate devices.

Testing and Standards: Performance Test: Test results in the report demonstrate that the bladder function of the UHC APL reprocessed compression sleeve after reprocessing six (6) times were substantially equivalent to the new original ALP® Sleeves.

Safety Efficacy: Testing indicated no adverse effects or complications resulting from reprocessing the UHC APL sleeve device six (6) times. The tests conclude that the UHC APL reprocessed sleeve device is safe and effective, and performs substantially equivalent to legally marketed new original ALP® sleeve device.

Biocompatibility: The UHC APL reprocessed sleeve device was tested for biocompatibility according to the ISO 10993-1 test Matrix. The results indicate substantial equivalence in all required categories to the predicate device.

Intermediate Disinfection and Cleaning Efficacy: Tests conclude that UHC APL reprocessed sleeve device passed the intermediate level of disinfection testing. The new original ALP® sleeve predicate has the technological advantage over the reprocessed device, having never been reprocessed.

Cleaning Efficacy: Nelson Labs' TOC Procedure SOP/CHM/0411.1 was used to test Total Organic Carbons (TOC) ppb of the reprocessed sleeves that have been contaminated on 44 in ^{2} and cleaned using the Kendall K031189 cleaning process. UHC APL reprocessed sleeve device passed having scored equal to or less than the PBB of TOC on the new sleeve.

Conclusion: Device testing and comparisons of specification determined that UHC APL reprocessed sleeve devices are substantially equivalent to the predicate devices with respect to device intended use and performance, as well as product disinfection, packaging, labeling and safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

University of Utah Hospitals and Clinics
c/o Mr. Brent Alm
50 North Medical Drive
Salt Lake City, UT 84132

Re: K080551
University Health Care Processed Alternating Leg Pressure
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 28, 2008
Received: February 28, 2008

Dear Mr. Alm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

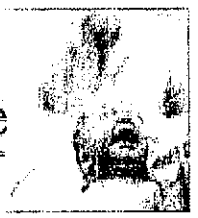
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

University Health Care



Indications for Use

510(k) Number (if known): K080551_____

Device Name: UHC APL_____

Indications for Use: The University Health Care Reprocessed Alternating Leg Pressure (UHC APL) sleeve device reprocessing methods do not change the intended use of the original manufacturer Healthcare Service and Supply ALP® (K000303) alternating leg pressure sleeve device. Both are sequential compression sleeves to be used by patients as a non-invasive therapeutic method to prevent deep vein thrombosis and resulting pulmonary embolism.

Prescription Use _____X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bolduc

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080551